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Financing Drug Research: What are the Issues?

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Issue Brief

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Financing Drug Research: What Are the Issues?

Executive Summary

Rising drug prices are placing an ever larger burden on family budgets and the economy. The Center for Medicare and Medicaid Services estimates 2004 expenditures at $207 billion (more than $700 per person), and projects that annual spending will grow to more than $500 billion by 2013 (more than $1,600 per person). The immediate cause of high drug prices is government granted patent monopolies, which allow drug companies to charge prices that are often 400 percent, or more, above competitive market prices.

Patent monopolies are one possible mechanism for financing prescription drug research. Rapidly increasing drug costs, and the economic distortions they imply, have led researchers to consider alternative mechanisms for financing drug research. This paper outlines some of the key issues in evaluating patents and other mechanisms for financing prescription drug research. It then assesses how four proposed alternatives to the patent system perform by these criteria.

The most obvious problem stemming from patent protection for prescription drug is the huge gap it creates between the cost of producing drugs and the price. In addition, to making drugs unaffordable in many cases, high drug prices also lead to enormous economic inefficiency.

Patent monopolies cause economic distortions in the same way that trade tariffs or quotas lead to economic distortions, but the size of the distortions are far greater. While trade barriers rarely increase prices by more than 10 to 20 percent, drug patents increase prices by an average of 300- 400 percent above the competitive market price, and in some cases the increase is more than 1000 percent. Simple calculations suggest that the deadweight efficiency losses from patent protection are roughly comparable in size to the amount of research currently supported by the patent system – approximately $25 billion in 2004. Projections of rapidly rising research costs, and therefore a growing gap between price and marginal cost, imply that the deadweight loss due to drug patents will exceed $100 billion a year by 2013.

As economic theory predicts, government granted patent monopolies lead not only to deadweight efficiency losses due to the gap between the patent protected price and the competitive market price, but also to a variety of other distortions. Among these distortions are:

1) excessive marketing expenses, as firms seek to pursue the monopoly profits associated with patent protection – data from the industry suggests that marketing costs are currently comparable to the amount of money spent on research;

2) wasted research spending into duplicative drugs – industry data indicates that roughly two thirds of research spending goes to developing duplicative drugs rather than drugs that represent qualitative breakthroughs over existing drugs;
3) the neglect of research that is not likely to lead to patentable drugs;
4) concealing research findings in ways that impede the progress of research, and prevent the medical profession and the public from becoming aware of evidence that some drugs may not be effective, or could even be harmful.

In addition, the patent system for financing prescription drug research poses large and growing problems in an international context. Disputes over patent rules have increasingly dominated trade negotiations. Furthermore, problems of enforcement have persisted even after agreements have been reached. These problems are likely to worsen through time, as the pharmaceutical industry seeks to increase the amount of money it extracts from other countries through patent rents.

This paper examines four alternatives to the patent system:

1) A proposal by Tim Hubbard and James Love for a mandatory employer-based research fee to be distributed through intermediaries to researchers (Love 2003);
2) A proposal by Aidan Hollis for zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use (Hollis 2004);
3) A proposal by Michael Kremer for an auction system in which the government purchases most drug patents and places them in the public domain (Kremer 1998);[2] and
4) A proposal by Representative Dennis Kucinich to finance pharmaceutical research through a set of competing publicly supported research centers (Kucinich 2004).

All four of these proposals finance prescription drugs in ways that allow most drugs to be sold in a competitive market, without patent monopolies. These proposals also would eliminate many of the economic distortions created by the patent system. The table below summarizes the assessment of these various systems based on the discussion in the text.

[2] Hay and Zammit (2002) suggest a variant of the Kremer auction system, in which only patents that are especially important for public health (e.g. an AIDS vaccine) are put up for auction and bought by the government. Under this system, many drug patents would remain privately held, with drugs sold in the same manner as they are now.

Rating Methods of Supporting Prescription Drug Research

	Patent System	Hubbard and Love	Hollis	Kremer	Kucinich
Marginal Cost Pricing	**1**	**5**	**5**	**4**	**5**
Excessive Marketing	**1**	**5**	**3**	**4**	**5**
Adequate Financing For Bio-Medical research	**4**	**4**	**5**	**3**	**4**
Incentives for Copycat Research	**1**	**5**	**4**	**4**	**5**
Political Interference in Research priorities	**4**	**3**	**3**	**5**	**3**
Secrecy of Research Findings	**1**	**4**	**2**	**2**	**5**
International Coordination	**2**	**4**	**4**	**4**	**4**

Ratings are on a scale of 1 to 5, with 5 being the best from a social standpoint. See text for the basis for the ratings.

These proposals, along with other plausible alternatives to the patent system, deserve serious consideration. Current projections for drug spending imply that patent supported prescription drug research will lead to ever larger distortions through time. For this reason, it is important to consciously select the best system for financing prescription drug research, not to just accept the patent system due to inertia.

Introduction

In response to the exploding cost of prescription drugs, there has been growing interest in alternatives to government granted patent monopolies as a mechanism for supporting prescription drug research (see Baker and Chatani, 2002; Kremer, 1998; Love, 2004; Hollis, 2004; Dimasi, 2004). It is widely recognized that, left to itself, the market will not support an adequate amount of bio-medical research – companies that pay for research will not be able to recoup their research expenses if they sell their products in a competitive market. However, it does not follow that government granted patent monopolies are the best supplement to the market.

The current reliance on patent monopolies is due to the fact that the system is a surviving legacy of the feudal guild system, it is not the result of economic analysis demonstrating its superiority. The recent questioning of this system is long overdue. With prescription drugs accounting for a large and rapidly growing share of GDP, inefficiencies in their production will impose an ever higher cost through time. (The Center for Medicare and Medicaid Services [CMS] projects that prescription drug spending will be equal to 2.8 percent of GDP by 2013).[3]

This paper lays out some of the key issues in assessing the relative merits of different systems. Some of these issues can be reasonably well quantified, such as the excess cost to consumers that results from patent monopolies in prescription drugs. The answers to other questions, such as the impact of alternative incentive mechanisms on innovation, may necessarily be more speculative, but it can still be helpful to draw out more clearly what is at issue.

In principle, it should be possible to reach some agreement on the advantages and disadvantages of various mechanisms for supporting prescription drug research. In reality, that may prove difficult. There is a huge amount at stake in this debate. Most immediately there are tens of millions of people in the developing world whose survival depends on drugs, which will be altogether unaffordable (even with outside aid) if they are sold at the patent protected prices in rich nations. On the other side, the major pharmaceutical companies depend on the current patent system for their survival. They are prepared to devote considerable resources to defending their interests in this debate.

Outlining the Problem–

It is worth noting two features of the prescription drug market that add another level of complexity to this problem. First, the immediate consumer is often not the payer for

[3] See Heffler, S., S. Smith, S. Keehan, M. Clemans, M. Zeeza, and C. Truffer, "Health Spending Projections Through 2013," *Health Affairs*, February, 2004, table 2.

prescription drugs. In most cases, at least in the United States, the bulk of the cost of prescription drugs is borne by a third party, either the government or a private insurer. This complicates issues because a third party payer means that patients, and their doctors, have relatively little reason to take the price of drugs into account as long as the third party will pick up the expense. From the standpoint of the drug industry, their sales effort must focus as much on ensuring that the third parties (insurers and the government) pick up the bills, as persuading doctors and patients to use their drugs.

The second difference between the prescription drug market and most other markets is the huge asymmetries of information between the buyers and the sellers. Patients will in general not be able to know which drugs are best for them before they use them, and will often not even be able to make this determination after the fact. Almost no patients will be able to assess for themselves the risk of side effects and long-term harm that may be associated with some drugs. In many cases, even their doctors will not be able to accurately assess these risks, since they may not be familiar with all the research on the topic. This problem is increased insofar as drug manufacturers have incentive to misrepresent existing research or to conceal research findings from the public and the medical profession.

The problems of third party payers and asymmetric information complicate efforts to design an efficient system for financing pharmaceutical research. The fact that the patient is often not the one who immediately pays the bill means that there is an unavoidable political element in determining the demand for a particular drug. The demand will depend not only on the value the patient assigns to the drug (as is the case with most consumer products), but will also depend on whether the third party payer can be persuaded or forced to pay the cost of the drug. Similarly, the fact that patients are typically not fully informed about the benefits and risks of particular drugs creates the potential for large profits by concealing information. These problems must be kept in mind when assessing methods for financing prescription drug research.

Marginal Cost Pricing

Economists typically place an enormous value on promoting marginal cost pricing. This is a basic condition of economic efficiency. When prices exceed marginal cost, for example due to trade barriers or government regulations, it imposes a deadweight loss on the economy. Consumers are willing to buy goods or services at a price that is more than the cost of production, but are denied the opportunity. In such situations, it is easy to show how all parties can gain (in principle) by reducing the price to the marginal cost and redistributing some of the resulting gains from consumers to producers.

This is exactly the argument that has motivated the quest to reduce trade barriers and government regulation over the last quarter century. Of course the gaps between price and marginal cost that result from most trade barriers or regulations are trivial compared to the gaps that are created by patent protection in the pharmaceutical industry. For

example, the steel tariffs that President Bush imposed in 2002 hit their peak at 30 percent for a narrow category of steel products. By contrast, the average increase in price for pharmaceuticals due to patent protection is probably close to 400 percent, with the gap in many cases exceeding 1000 percent of the marginal cost. [4]

The deadweight loss associated with such large gaps between price and marginal cost are likely to be substantial. Table 1 shows a set of calculations of deadweight loss in the United States, assuming that the competitive market price is equal on average to 30 percent of the patent protected price. The first three rows in the table assume that all drugs have the same mark-up. The bottom three rows shows calculations of deadweight loss assuming that for half of patented drugs, the competitive price would be 50 percent of the patent protected price and for the other half, the competitive price is equal to 10 percent of the patent protected price.

Table 1

Deadweight Loss in the United States from Patent Protected Drugs

All drugs have same mark-up

Elasticity = 0.15 percent -- deadweight loss = $10.7 billion
Elasticity = 0.30 percent -- deadweight loss = $22.7 billion
Elasticity = 0.50 percent -- deadweight loss = $40.9 billion

Varied mark-ups

Elasticity = 0.15 percent -- deadweight loss = $23.4 billion
Elasticity = 0.30 percent -- deadweight loss = $29.4 billion
Elasticity = 0.50 percent -- deadweight loss = $55.4 billion

Source: Author's calculations.[5]

While it would be desirable to have more precise estimates of the deadweight loss to consumers due to the gap between patent protected drug prices and the competitive

[4] These figures are based on comparing drug prices between the United States and countries where drugs are either subject to price controls or where the same drugs are produced as generics (see Baker and Chatani, 2002, "Promoting Good Ideas on Drugs: Are Patents the best Way?" Center for Economic and Policy Research [http://www.cepr.net/promoting_good_ideas_on_drugs.htm]) . Several AIDS drugs provide examples where the price increase due to patent protection exceeds 1000 percent. In some cases, generic versions are now produced in India at prices in the range of $100 to $300 a year. A year's supply of the brand versions in the United States for the same drugs would often cost $5,000 to $10,000.

[5] These calculations use constant elasticity of substitution utility functions with the elasticities shown in the table. The first three rows assume that all patent protected drugs experience a 70 percent decline in price in a competitive market, while the second set assumes that the price of half of all drugs decline by 50 percent and half by 90 percent in a competitive market. The calculations in the table are based on $200 billion in annual prescription drug spending, slightly less than the $207.9 billion in spending projected by the CMMS for 2004 (Heffler, S., S. Smith, S. Keehan, M. Clemans, M. Zeeza, and C. Truffer, "Health Spending Projections Through 2013," *Health Affairs*, February, 2004.)

market prices, these calculations give some ideas of the magnitudes involved. The size of the deadweight losses calculated in the table range between 0.1 and 0.5 percent of GDP. These deadweight losses are at least an order of magnitude larger than the efficiency losses that are typically addressed with most economic policies, such as trade liberalization.

The calculations of dead weight loss are also are approximately equal to the amount that the industry currently claims that it is pending on pharmaceutical research in the United States. This means that for every dollar of research financed through the patent system, the economy loses approximately one dollar of output as a result of the waste attributable to the gap between price and marginal cost created by patent protection.

While the figures in table 1 are already quite large, the efficiency losses associated with patent protection for pharmaceuticals will increase substantially over the next two decades, if projections for drug expenditures prove correct. The CMS projects that spending on prescription drugs will rise to $519.8 billion by 2013. If the mark-ups over the competitive price remained constant, this would imply that the annual value of the deadweight loss due to patent protection would rise to close to $60 billion annually by 2013, in the middle scenario shown in table 1, approximately 0.4 percent of projected GDP.

However, much of the projected increase in expenditures on drugs is likely to be attributable to increased mark-ups, not the usage of more drugs. Dimasi (2003, p 180) estimated that industry's research costs have been rising at a real annual rate of 7.4 percent. At this rate, real per drug research costs double every ten years. If the mark-up over the competitive price is proportional to the per drug research costs, then the average mark-up in 2013 will be twice as high as it is presently. This means that the deadweight loss would rise even more rapidly than drug expenditures. In the middle elasticity scenario, the deadweight loss would be equal to $105 billion in 2013, or 0.6 percent of GDP. In short, if Dimasi's projections of the growth in research costs prove accurate, then the implications for the size of the deadweight loss under the current patent system are staggering.

While the size of the deadweight losses associated with patent protection for pharmaceuticals is substantial, other costs that are attributable to patent monopoly profits could prove to be even larger. The monopoly profits available on additional sales provide firms with an incentive to engage in activities that could be of little social value and possibly even have negative value. Among the items in the first category is marketing and advertising. The drug industry has an incentive to spend large amounts of money promoting its products, precisely because of the monopoly profits that patents allow. The profit maximizing levels of marketing and advertising would be far lower if drugs were sold in a competitive market.

There is an important economic distinction between the money that goes to drug companies as profit, due to above marginal cost pricing, and the additional money spent

on advertising and marketing as a result of above marginal cost pricing. The money in first category is a simple redistribution from consumers to producers, this can have important consequences for the distribution of income, but is not inefficient in an economic sense (the deadweight loss due to the higher prices is inefficient). In contrast, the money used to finance additional advertising and marketing is a second source of economic inefficiency associated with above marginal cost pricing. In this case, economic resources (workers, material, capital) are being used to undertake tasks that would not be profitable, if drugs were sold in a competitive market. These resources could, in principle, be used more productively in other areas of the economy. For this reason, advertising and marketing are a major source of economic inefficiency that is an inevitable result of patent protection for prescription drugs.

Data from the pharmaceutical industry indicate that it spends approximately as much on advertising and marketing as it does on research.[6] While it is useful to have accurate information disseminated to doctors and the public (the optimal amount of marketing is not zero), it is reasonable to assume that only a small share of these expenditures can be viewed as useful in this respect. The sole purpose of the industry's marketing expenditures is to increase the use of its drugs – there is no economic value in spending that is intended to convince doctors or patients that a drug is better than available alternatives, when this may not be the case.

The fact that there is asymmetric information in the drug market, and often third party payers, adds hugely to the inefficiency. The existence of asymmetric information, where the drug company will generally know more about its product than doctors, and much more than patients, creates a situation in which companies stand to make huge profits by making misleading or even false claims about their drugs. There are numerous well-documented instances in which drug companies have withheld research findings from the public or even misrepresented their findings. This is a predictable outcome of a situation in which firms can earn above normal profits as a result of government granted patent monopoly.

The cost to the public from inaccurate and incomplete information can be enormous. Patients may receive inferior treatment if they or their doctors are misled about the effectiveness of drugs or improperly persuaded to prescribe a particular drug.[7] They may even be directly harmed if drug companies conceal information about dangerous side effects. While the government can hope to limit these sorts of abuses through regulation and penalties, the gap between patent protected prices and production costs is very large. Therefore, it is unreasonable to believe that government action can completely eliminate this behavior when the potential profits are so great. While there is always some risk of

[6] PhRMA, the pharmaceutical industry's trade association, reported that in 2000, the industry employed 87,810 people in sales and marketing compared to just 48,527 in research [www.pharma.org/publications/publications/profile01/app_a3.phtml].

[7] In some cases, marketing efforts take the form of outright bribes as drug companies share some of their monopoly profits with doctors (e.g. see " As Doctors Write Prescriptions, Drug Company Writes a Check," *New York Times*, 6-27-04; A1).

fraud or misrepresentation in scientific research, this risk is clearly much greater in the context of a patent system that can offer enormous rewards for such anti-social behavior.

The fact that third parties often pay for drug purchases also complicates the situation enormously in the case of patent monopolies. This creates a situation in which drug company profits often depend on successful political efforts to persuade the third party to pay for their drugs. In the case of the government, this typically involves lobbying efforts by drug companies to ensure that the relevant government programs will pay for their drugs (e.g. see "Making Drugs, Shaping the Rules," *New York Times*, 2-1-04;, Section 3, page 1). In the case of private insurers, drug companies must persuade the companies to add their drugs to approved lists. This can involve major campaigns directed against specific insurers.

There are two reasons why the fact that drug sales efforts often involve appealing to third parties is important. First, these sales/lobbying efforts also use resources (e.g. lawyers, lobbyists, "grassroots" disease groups) that are a direct source of economic waste. Second, if the use of the drugs depends on a decision by a third party rather than the patient, then there is an inevitable political element to it. This means that the choice of drugs is not simply a matter decided by the patient (with the advice of a physician), rather it will frequently depend on the decisions made by the third party payer. The classic situation of "consumer sovereignty" that economists extol, does not exist in this market.

The fact that there is a large and growing divergence between price and marginal cost in the pharmaceutical industry also provides incentives for the production of counterfeit drugs. When it is possible to manufacture drugs at prices that are often less than one tenth of the patent protected price, and sometimes just 1 or 2 percent of this price, there will be enormous incentives for individuals to manufacture unauthorized versions of these drugs, in the same way that huge mark-ups provide incentives for smuggling illegal drugs like cocaine or heroin.

Making the drugs available at a lower price would actually increase economic efficiency, if the quality of the drugs could be ensured. However, this will not generally be the case with drugs produced or sold in violation of U.S. laws. Many patients may still opt to buy unauthorized versions of drugs, if those are the only drugs that they can afford, but they could suffer severe health consequences as a result.

The spread of unauthorized versions of drugs is an inevitable result of an increasing gap between price and marginal cost. Currently, much of the use of unauthorized versions of drugs in the United States involves the importation of drugs from other countries, which place a ceiling on patent protected prices. The quality of these drugs depends both on the regulatory structure in the country where the drug is sold and also on the reliability of the retailer. However, even if the path to purchasing drugs in other countries were somehow foreclosed, it is virtually certain that domestic manufacturers would fill the gap. Law enforcement (which has a substantial cost) can limit the production of unauthorized versions of drugs, but it cannot eliminate it altogether, just as laws in the Soviet Union did not prevent the sale of blue jeans on the black market.

To sum up, there are very good reasons – well known to all economists -- for preferring that drugs be sold in a competitive market with the price approximating the marginal cost of production. The gap between price and marginal costs under the current system of patent supported research leads to large and rapidly growing distortions. This includes denying drugs to patients who could afford them if they were sold at their marginal cost, the distortions also include the tens of billions of dollars spent each year on promoting drugs. Even more serious is the incentive that monopoly pricing provides firms to conceal or misrepresent research findings. Finally, a large gap between price and marginal cost will inevitably lead to the production of unauthorized versions of patent protected drugs. While these unauthorized versions make drugs available at a lower costs to patients, their quality cannot be ensured since illegal markets are unregulated.

Research Incentives

While patent protection for prescription drugs clearly leads to substantial economic distortions as a result of the fact that it raises drug prices far above marginal cost, it does have the advantage of providing incentives to undertake research that would be lacking in a competitive market. However, it is not apparent that the incentives provided by patent monopolies are the most efficient way to direct research, even ignoring the inefficiencies that result from raising drug prices far above the marginal cost.

In principle, research should be directed towards areas where it would have the greatest expected marginal social benefit. Defining the greatest marginal social benefit poses enormous difficulties – most obviously there would be a very different answer depending on whether the question was posed as the benefit for which people are willing to pay the most money or whether it is defined as providing the most medical benefit for the largest number of people, by some non-market criteria. However, this issue can be side-stepped for purposes of this discussion, since many of the same problems arise in designing an optimal system for financing drug research, regardless of which definition is used.

The key issues in choosing a method for financing pharmaceutical research are ensuring that researchers have strong incentives to pursue all avenues of useful research, and that they are not encouraged to pursue lines of research that have little social value. The four main potential problems are:

1) the incentives for pursuing useful research are inadequate;
2) incentives are created through market distortions for pursuing less productive lines of research;
3) incentives are created through political interference to pursue less productive lines of research; and
4) incentives are created to obstruct the free flow of research findings, thereby impeding the progress of research.

Each of these types of problems is briefly outlined below.

1) While the basic thrust of the first issue – that researchers may not have sufficient incentive to produce useful areas of research – is straightforward, its full ramifications may be more complex than they first appear. Obviously, in a competitive market, there is very little incentive to pursue research of any sort – all competitors will have access to the results of research findings and will be able to sell drugs at prices that are too low to allow recovery of research costs. However, there is no obvious way to ensure that there will be incentives to pursue all avenues of useful research.

A patent system provides an incentive to pursue some avenues of useful research – specifically those areas of research that are likely to result in the discovery of patentable products. However, this excludes large areas of potentially useful research, such as research on the beneficial effects from changes of diet and exercise, problems that result from workplace and environmental hazards, or new uses of drugs that are no longer subject to patent protection. In addition, it will likely be difficult to support many areas of basic research, where any potentially useful drugs or products are distant prospects, through the patent system.

The current practice of directly funding large amounts of public research through the National Institutes of Health and other public agencies, in addition to tax subsidies for non-profit research, is an explicit recognition that the patent system does not provide adequate incentive to support all useful forms of biomedical research. At present, the quantity of publicly supported or subsidized research in the United States is approximately equal to the amount of research supported through the patent system.[8]

While there is little open dispute about the usefulness of this research, as current levels of funding are regularly approved with almost no political opposition, there is no reason to believe that this funding level is adequate, or that the direction of this research spending is sufficiently effective to ensure that all socially useful lines of research (where the expected marginal benefit exceeds the cost) are pursued. There is no obvious way for determining the amount of useful research that is not supportable through a specific patent system and the amount that can be effectively supported by patent monopolies, but current spending levels suggests that the first category is comparable in magnitude to the second. Unless public support is very effectively targeted, then it is likely that substantial areas of socially useful research would be neglected.

In addition to the possibility that areas of socially useful non-patentable research will be neglected, the third party payer system also raises the possibility that there may not even be sufficient incentive to carry through some lines of research that are in principle supportable through patents. If the government, or several large insurers, were to refuse to cover the costs of some types of drugs, then the patent system would provide insufficient incentive to pursue their development. Such a refusal could be the result of explicit political considerations (e.g. drugs that end pregnancy), corruption (e.g. the result

[8] In 2000, PhRMA estimated that the industry spent $19.6 billion on research in the United States. The budget for the NIH for 2000 was $17.9 billon.

of a current patent holder's efforts to impede competition), or simply bias and ignorance. While individuals could still purchase drugs that are not covered by third party payers, there is less incentive to research such drugs, since the market will clearly be smaller.

2) The possibility that market distortions will create incentives to pursue less useful lines of research is straightforward. The monopoly rents created by a patent system provide incentives to develop drugs that may provide very little social benefit relative to existing drugs. If a new drug can capture part of the rents earned by existing drugs, then firms will have incentive to pursue its development. In the context of a patent system the existence of duplicative drugs can have the effect of lowering prices by creating competition, however, there would be little social benefit in researching such drugs if they were being sold in a competitive market.[9] The Food and Drug Administration has rated 76 percent of the drugs it approved in the nineties as being duplicative rather than breakthrough drugs.[10] According to a study commissioned by the Pharmaceutical Manufacturers and Researchers Association (Ernst and Young, 2001), it cost the industry almost as much to research duplicative drugs as breakthrough drugs. This implies that the market distortions created by patent monopolies is directing the bulk of current research spending toward the development of duplicative drugs instead of new breakthrough drugs.

3) There is a real risk in any mechanism for publicly supported research that political interference can direct research spending towards less useful ends. This could be the case if powerful political actors are able to distort the research agenda of whatever public entities are setting the priorities for research spending. This could mean that some types of health problems are wrongly prioritized, or more likely, that some researchers are favored for grants, even when their records would not warrant public support. By contrast, under the patent system, the decision over which drugs to research is made based on expected profitability.

However, this distinction is not as clear cut as it may first appear. In a patent system, the question is not only whether a new drug may be potentially useful, but also whether, and how much, a third party will pay for the drug. This also involves political considerations. As noted in the prior section, the profitability of a new drug will often depend on whether the government or insurers can be forced to pay a premium in excess of the cost of existing drugs. This will depend not on an abstract assessment of the drug's merits, but on the ability of the drug's manufacturer to influence the decision of the government and/or private insurers. In short, there are ample opportunities for political considerations to

[9] Copycat drugs can have some benefits since different patients respond better to some drugs than others. Also, since many patients must take drugs for a variety of problems, some drugs might be better suited for being taken in combination with other drugs. For these reasons, research into the development of copycat drugs is not completely useless, but it almost certainly would provide less benefit than research into the development of new breakthrough drugs.

[10] U.S. Food and Drug Administration, "NDAs Approved in Calendar Years 1990-2001 by Therapeutic Potentials and Chemical Types," December 31,2001. [http://www.fda.gov/cder/rdmt/pstable.htm.]

affect the allocation of research spending even within the system of patent supported drug research.

4) The last issue is one of the important perverse incentives created under the patent system. Any system that provides incentives for successful research will always provide some incentive for secrecy, as researchers will want to ensure that they get credit for the work they have performed. This will be the case with purely academic research as well as with research supported under the patent system. However, the problems associated with secrecy with purely academic research are typically limited. Once researchers have the opportunity to make work publicly available under their name, they have an incentive to ensure that the work is as widely distributed as possible, since their rewards will generally depend on the extent to which this work is found useful by other researchers.

However, the reward structure of the patent system creates two distinct sets of incentives to limit disclosure. First, if research is likely to lead to patentable findings, then a drug company has an incentive to minimize its disclosure of information. When it does file for patents, the incentive is to only make available the information necessary to obtain the patent, and to withhold any additional information which could aid rival firms.

Second, drug manufacturers have incentive to withhold any research findings that reflect poorly on their product. This would include findings that call into question the effectiveness of their products and also findings that suggest that their products may be harmful.[11] While the threat of legal liability may limit the extent to which firms will withhold information, especially evidence of harmful effects, enforcement will never be perfect. Where there are large incentives to conceal information – as is the case with the patent system -- it is reasonable to assume that drug companies will be able to conceal some amount of negative research findings. In the absence of effective enforcement mechanisms, the quantity and importance of concealed research findings is likely to be large.

International Coordination

A final set of issues that needs to be addressed in evaluating mechanisms for supporting drug research concerns international coordination. The basic point is that the cost of research should be shared in some way internationally – once research findings are known, they are in principle freely available to the whole world regardless of how they are financed. While the exact formula for sharing can be debated, there is general

[11] For example there has been a recent controversy over the effects of antidepressant drugs on children. Doctors are uncertain at present about their usefulness in part because many of the key studies are being kept secret by firms that financed them (see "Antidepressant Use in Children Soars Despite Efficacy Doubts," *Washington Post,* 4-18-04;A1).

agreement that countries at comparable levels of development should bear a roughly equal burden, with the poorest countries bearing little or none of the expense of supporting research. In principle, any mechanism should be both fair – achieving agreed upon goals for distributing the burden – and efficient, with the lowest feasible enforcement costs.

Scoring the Proposals

This section examines how four recent proposed alternatives to the patent system measure up in dealing with the issues raised in the prior sections. This discussion is necessarily speculative, both because there is not sufficient data to evaluate many key factors and because the proposals are not fully developed at this point.

The four proposed alternatives to the patent system are:

1. A proposal by Tim Hubbard and James Love for a mandatory employer-based research fee to be distributed through intermediaries to researchers (Love 2003);
2. A proposal by Aidan Hollis for zero-cost compulsory licensing patents, in which the patent holder is compensated based on the rated quality of life improvement generated by the drug, and the extent of its use (Hollis 2004);
3. A proposal by Michael Kremer for an auction system in which the government purchases most drug patents and places them in the public domain (Kremer 1998); and
4. A proposal by Representative Dennis Kunich to finance pharmaceutical research through a set of competing publicly supported research centers (Kucinich 2004).[12]

These proposals are described in somewhat more detail below.

Hubbard and Love

The proposal by Hubbard and Love is part of a larger effort to suggest alternatives to patent financed drug research in both a national and international context. The authors have written numerous pieces (e.g. Hubbard and Love, 2004) suggesting arrangements under which countries could meet obligations to finance an appropriate share of world-wide pharmaceutical research, without necessarily implementing U.S. type patent rules for drugs. Under this particular proposal, which appears to be designed based on the current U.S. employer-based health care system, employers would have an obligation to pay a certain amount (e.g. $100 to $200 per year) for each covered worker, to a designated research firm or intermediary.

Hubbard and Love leave open the criteria by which research firms or intermediaries would actually allocate funds. They suggest that some may opt to directly support

[12] This bill was largely based on the work in Baker and Chatani (2002).

pharmaceutical research – along the lines of NIH, while some may opt for using prize mechanisms to promote worthwhile innovations. Since the allocation of research funds by employers would be done on a competitive basis, presumably they would seek out research firms or intermediaries that had established the best track records in promoting useful research.

Hollis

The proposal by Aidan Hollis sets up a system in which firms would acquire patents, much as they do under the current system, except they would be required to make use of the patent freely available through a zero cost compulsory license. The usefulness of the patent would then be assessed by a government agency, which would assign it a rating based on the extent to which it improved the quality of life and/or extended life expectancy compared with the next best alternative treatments. The agency would then compensate the patent holder each year based on the rating and the annual sales of the drug. (The rating would have to be reconsidered each year, due to the fact that new drugs may change its rating.) Hollis calculates that a pool of $60 billion would be needed each year in the United States to ensure adequate incentives to promote innovation.

Kremer

Michael Kremer also proposed a system in which firms register drug patents in a manner similar to the current system. Under his plan, most patents would get purchased by the government at regular auctions and then get placed in the public domain, where they could then be manufactured as generics. The purpose of the auctions is to ensure that the patent holders are properly compensated. The government would act as a passive observer at these auctions – in most cases buying the patent at the winning price. However, in some cases, the government would allow the high bidder to actually purchase the patent. The patent holder would then be entitled to the same protection as is available to patent holders at present.

The purpose of allowing some percentage of patents to actually be sold to the bidders is to ensure that the auctions are informative. If the bidders know that there is a substantial probability that they will actually end up buying the patent, then they have incentive to study the patents and estimate their proper price. In principle, this should ensure that the prices paid by the government represent the fair market value of patents, even if it means that some drugs will still be subject to patent monopolies and sell for above their marginal cost.

Kucinich

The proposal by Dennis Kucinich establishes a set (e.g. 10) of publicly funded research corporations to conduct drug research. The total funding available to these companies would be roughly equal to the amount of research in the United States currently

supported through the patent system (approximately $25 billion a year). The corporations would each fund research, under an obligation to make all findings fully public in a timely manner, and would place all patents in the public domain.[13] The system also provides for a substantial pool of prize money (e.g. $500 million annually) which would be awarded for outstanding breakthroughs to researchers or teams of researchers.

Under the Kucinich proposal, existing drug patents would remain in effect (although it does not preclude price controls or parallel imports), and pharmaceutical companies could still obtain new patents. However, they would run the risk that the new drugs they develop would be competing with comparable drugs that are being sold as generics.

Common Features of the Proposals

The key feature that all four of these proposals have in common is that they largely eliminate the gap between price and marginal cost that is created by the current patent system.[14] The large and growing gap between the price and the marginal cost of drugs is the most apparent problem of the current patent system. It is understandable that the removal of this gap would be the main focus of reform proposals. The removal of this gap immediately eliminates a quantity of deadweight loss -- attributable to higher consumer prices – that is approximately equal to the amount of patent financed research spending at present, and may be more than twice as much as the quantity of patent financed research spending within a decade. Of course, this gain is in addition to the transfers from producers to consumers in the form of lower drug prices.

The key question in assessing these four alternative proposals, against each other and against the existing patent system, is how they stack up in providing the right set of incentives. The discussion below assesses the extent to which the proposals provide the appropriate incentives to carry through research into new drugs.

1) Sufficient incentives for productive research

It is difficult to have much basis for answering this question, since it is not clear what sort of incentives are necessary. As was noted earlier, close to half of all biomedical research in the United States is currently supported by the government, primarily through the NIH. There is little dispute that this money is very productive, with the research leading to

[13] The patents would actually be subject to a "copyleft" type principle. Any researcher or producer can freely use any patents developed through this system, as long as they did not attempt to use a patent to restrict the sale of any subsequent innovations.

[14] It is not clear that all drugs would be priced at marginal cost. First, there would be an issue as to how the transition to the new system is dealt with under all four proposals. In addition, the Kucinich proposal doesn't preclude the possibility that some companies may wish to continue to operate under the current patent system and compete with the drugs developed through the alternative system. Also, under the Kremer proposal some percentage of new drug patents would remain in private hands, with firms allowed monopoly marketing rights, as is the case at present.

many important breakthroughs. Given the track record of NIH, it might at first seem reasonable to believe that if direct funding was simply extended (with the scope of research obviously expanded), then directly funded research could readily replace the research currently supported by patent monopolies.

However, NIH research is heavily tilted towards basic scientific research, as opposed to the development and testing of new drugs. It has been argued that the nature of the research problems being addressed in developing and testing drugs is inherently less interesting than the problems dealt with in basic research, and therefore is not as inherently attractive to researchers (Kremer 2000, p 26). In other words, researchers may be willing to undertake basic research for the sorts of compensation available through NIH salaries and grants, but they would require much higher levels of compensation to engage in the more mundane research necessary to develop new drugs.

It is not clear how this claim can be evaluated, and its implications are even less clear. First, it is not clear how one could determine if researchers tend to view the development and testing of new drugs as inherently less interesting than the more basic research typically supported by NIH funding. Furthermore, if in fact the research problems being addressed in the development and testing of drugs are more mundane than those confronted in basic research, then presumably the skills involved are less scarce. If this is the case, then it is difficult to see why extraordinary rewards would be expected for work that may require rather common skills.

The fact that the work may be extremely valuable from a social standpoint is largely irrelevant, if a large number of people possess the necessary skills. For example, a firefighter may save tens or hundreds of lives during his or her career, but the compensation for firefighters is relatively modest, because there are large numbers of people who do, or can, possess the necessary skills. Similarly, if the research tasks involved in developing and testing drugs are really routine and mundane, then there are presumably a large number of people who possess, or could possess, the necessary skills. For this reason, it is not clear how much compensation is necessary to ensure that researchers have incentive to actively pursue socially useful lines of research.

It is also not clear that the actual researchers who accomplish major breakthroughs are always very well compensated at present. Although there are undoubtedly examples of researcher-entrepreneurs, who are able to lay claim to the patents from their research and then reap most of the subsequent profits, this is certainly not always the case. In many situations, the researchers, or teams of researchers, that achieve major breakthroughs will be employees or working under contracts that prevent them from claiming the rights to patents based on their research. While employers presumably reward researchers for major innovations, most researchers would only get a small fraction of the profits that a drug company may earn from a blockbuster drug. If this is the case, then it suggests that it is not necessary to provide extraordinary rewards (e.g. more than $10 million) to provide incentives for researchers to be innovative, since most of the researchers who are developing new drugs are not in a position to receive such rewards even under the current system.

If this accurately describes the situation faced by researchers at present, then the targets for incentives can be set considerably lower. Obviously researchers need to be paid professional salaries, as is the case for those supported by NIH salaries or working under NIH grants. In addition, it would be desirable to ensure that researchers are rewarded for extraordinary work – although there is no guarantee that this would be the case even with the current patent system.

While there is clearly a large degree of uncertainty about the size of the incentives necessary to support innovative research, there is no reason to assume that these four proposals would necessarily provide any less incentive than the current system. In the case of the Hollis proposal, the sums that would be in principle available to researchers and drug companies should be very comparable to what they currently receive. The major difference would be that they would receive their income based on a system of government payments determined by sales of their drugs and the ratings of these drugs on their usefulness compared to the best available alternatives. The rating system creates an additional complication – the rating board would have to assess the relative usefulness of each patent protected drug on an ongoing basis – but this would not on average reduce the amounts paid as compensation to drug companies or researchers.

It is worth noting, that the Hollis system is alone among these four proposals in maintaining the link between drug development and distribution. Under the Hollis proposal, drug firms' profits will depend directly on the frequency of the use of their drugs. For this reason, this proposal is likely to preserve the sort of sales and marketing network that exists at present. A substantial portion of the pool of money set aside to compensate drug companies for their research would therefore be used not only to support research, but also to pay for their sales and marketing efforts. By contrast, in the other three proposals, there is no direct incentive to the companies developing drugs to increase the sales of their drugs. Therefore any marketing would be carried through by manufacturers who are selling the drugs in a competitive market.[15]

The Kremer auction system would likely lead to a substantial reduction in compensation to drug companies for their patents due to the fact that, under this system, most patents are placed in the public domain. The value that bidders place on a new patent will be drastically reduced if patented drugs must compete with newly developed drugs that are being sold as generics. While this will lead to a situation in which firms receive less money for each patent, it is not clear how much this will reduce the funding available to support research.

[15] The optimal level of marketing is not zero, as it can provide useful information. However, for the incentives to be right, the social usefulness of all drugs (however determined) should be proportional to their mark-up. Even if the prices were set right among patented drugs, there would still be the problem that these mark-ups would be higher than with drugs whose patents had expired or the mark-ups available on treatments (e.g. exercise and nutrition) that did not involve patentable products. There is certainly no social interest in promoting drug based treatments over non-drug based treatments.

Under the Kremer proposal, firms would be relieved of the cost of marketing their drugs. The manufacturing and marketing of drugs would be separated from research and development.[16] This means that even though they receive less money for each patent, it need not mean that there is less money available to support research. Also, since the Kremer system would eliminate most of the incentive to research copycat drugs (there would be little market for copycats, when breakthrough drugs are selling at generic prices), even if less money was spent in total on research, the funding available to support research into innovative drugs may remain comparable to what exists under the current system. [17]

Both the Hubbard-Love and Kucinich proposals specify that an amount roughly equal to current levels of research spending would be allocated to financing pharmaceutical research. This should support an amount of research that is roughly comparable to the amount being supported under the current system.

However, under both systems there would likely be less incentive to carry through research into the development of duplicative drugs. In the case of the Hubbard-Love system, employers would be choosing between researchers and intermediaries when they allocate their pools of research funds. Presumably, employers would tend to contribute more funds to researchers and intermediaries that had a track record of producing important research breakthroughs, rather than developing duplicative drugs.

Under the Kucinich system, the research corporations would have to establish the effectiveness of their spending at regular intervals. This would presumably also discourage spending on the development of duplicative drugs. In addition, the rules applicable to these corporations would require regular disclosure of intermediate research findings. This would inform competitors of breakthroughs and failures, thereby reducing the amount of unnecessary duplicative research that exists under the current patent system. It is therefore reasonable to believe that the sums allocated under both the Hubbard-Love and the Kucinich plans would be adequate to support at least as much research into developing new drugs as does the current patent system.

There is one other important point about potential research efficiencies created by either the Hubbard-Love or Kucinich funding mechanism. The current structure of research relegates some areas of bio-medical research to public-non-profit sector (research into the effects of diet, exercise, the environment or the use of off-patent medicines) and other leaves areas of research to be supported through the patent system. Both of these funding mechanisms would leave no sharp distinction between these two different types of research.

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[16] Firms may opt to do both, but there would be no direct relationship between the two activities. Since most drugs would be sold as generics, they would typically not be manufacturing the drugs they had developed.

[17] PhRMA, the industry's trade association, commissioned a study which found that duplicative drugs cost approximately 90 percent as much to research as breakthrough drugs. Since approximately three quarters of all new drugs are duplicative of existing drugs, this implies that close to two-thirds of current research spending goes to develop duplicative drugs.

This could lead to much greater research synergies. For example, if research into the development of a particular drug provided evidence that a disease could be most effectively treated through changes in diet or exercise, under these systems researchers could continue to pursue their leads. By contrast, it is extremely unlikely that a pharmaceutical company would continue to support research which was likely to conclude that diet or exercise were effective treatments. While it may pass along relevant findings to researchers who could pursue such a path, it could not profit from pursuing this research itself.

Ultimately, the main difference between the Hubbard-Love proposal and the Kucinch proposal is over the decision to place the allocation of research funds in the hands of employers – who then choose among research corporations and/or intermediaries -- or whether it is more desirable to trust the allocation to a more centralized process. While both preserve elements of competition, neither has the direct consumer determining the allocation of research funds.

With the Hubbard-Love system, the allocation would depend on the decisions of employers (or presumably insurers in the case of people who buy their own insurance). Employers have no direct stake in ensuring that their research dollars are well used, so the efficiency of the allocation would depend on the extent to which they are public-minded enough to ensure that their funds go to an effective research corporation or intermediary. If employers took their responsibilities to allocate research money effectively serious, then this system could have an advantage over the Kucinich proposal in allowing for more effective competition among researchers. However, it is also possible that such a system could degenerate, with employers allocating funds based on friendships and kickbacks.

The Kucinich system relies on competition between the government research agencies – with the threat of being dissolved due to poor performance – to ensure that research dollars are allocated efficiently. However, if some, or most, of the agencies are poorly managed, and/or the review commissions are incapable of effectively evaluating each corporation's performance, then there is a risk that the research funds will be inefficiently allocated for sustained periods of time.

One potential mitigating factor, which only applies to the Kucinich system, is the requirement that all research findings be made public in a timely manner. This would allow the public to independently assess the effectiveness of the research agencies and their ability to pursue fruitful lines of research and to recognize failed research paths. This requirement of openness could limit many of the abuses that occur under the current system, and could persist in the other three systems outlined here.

2) market incentives for misdirecting research

As noted earlier, the patent system provides a powerful incentive for firms to carry through research into duplicative drugs, since it allows them to gain shares of the

monopoly profits earned under the patent system. All four of these proposals largely eliminate this problem, since they put in place a system in which most drugs would be sold at their marginal cost.

The one partial exception to this statement is the Kremer auction system. Under this system, some percentage of patents would continue to be held by private companies, who would take advantage of their patent monopoly to charge prices above marginal production cost. This would provide other firms with the same sort of incentive that exists under the current system to pursue research into duplicative drugs. However, this would affect a much smaller share of the market, since under the Kremer system, most patents would be in the public domain.

Under the other three systems, firms would have to justify spending on duplicative drugs by the additional value added through the development of these drugs. In the case of the Hollis system, the price assigned to the drug would depend on its incremental value over the existing alternatives – as determined by the rating body. Under both the Hubbard-Love system and the Kucinich system, firms would have to argue that money spent developing duplicative drugs contributed as much to promoting public health as if the same money had been spent developing breakthrough drugs.

3) risks of political interference in the direction of research

While the Kremer auction system seems largely protected from political interference, assuming that the integrity of the auctions can be ensured, there is some potential for political interference in the three other systems. In the case of both the Hollis system and the Kucinich system, there is the risk that political factors will directly affect the direction of research. In the case of the Hollis system, the opportunity for political interference would be in rating the usefulness of drugs. The interference could either take the form of imposing inappropriate values on the process (e.g. downgrading the value of new contraceptive pills/devices) or using political connections to influence the process. An example of the latter would be using political connections to increase the effectiveness rating of a particular drug.

Similar problems could arise with the Kucinich system. For example, Congress could prohibit the funding of research into certain areas.[18] Also, there would always be the possibility of using political connections to steer research funds to particular researchers. However, it is not clear that the latter sort of problems would be qualitatively different from what exists today in the private sector. Certainly, personal connections are often useful in the awarding of contracts in the private sector. While firms are ultimately held accountable for their performance by their ability to produce profits for investors, this does not guarantee that all contracts are awarded based on merit alone. Similarly, the public research corporations would ultimately be held accountable for their research record, which should limit the extent of political interference in the allocation of research

[18] However, since the Kucinich system does not require eliminating the current patent system, if the public agencies did not pursue a particular line of research, presumably private drug companies would fill the gap.

funds. The requirements of openness in awarding research contracts and their fulfillment should also limit the potential for abuses.

The main opportunities for political interference in the Hubbard-Love system is likely to be in the oversight of the system. Presumably, there will be a set of requirements that research corporations and intermediaries would have to meet to be eligible to be part of the system (e.g. they would have to use a certain portion of their revenue for research defined by some standard). They would also have to be restricted in their ability to provide kickbacks or "gifts" to employers in exchange for their support. This will require some policing of the system to determine who qualifies and to ensure that everyone plays by the rules. In principle, intermediaries or research corporations could use political connections to interfere with effective oversight.

It is important to note that the potential for political interference in determining research priorities is not qualitatively different under these alternative proposals than it is under the patent system. Certainly the research supported by NIH has frequently been the target of political intervention. Second, the ability of firms to profit from their patents often depends on their ability to persuade the government and/or private insurers to pay for a particular drug. This process invites political interference. Therefore, while it is appropriate to be concerned about the potential for political interference in the allocation of research funds in these alternative systems, it would be wrong to imagine that this problem does not arise under the current system.

4 Concealing or Distorting research findings

The final issue to consider between these four systems is the extent to which they create incentives to conceal or distort research findings. As noted earlier, this can be a major issue with the patent system. Early in the development process, companies have incentive to keep findings secret until they are confident that they have laid claim to all the potentially profitable patents based on a line of research. After drugs are placed on the market companies have incentive to keep findings secret that may undermine the market for their drugs, by raising questions as to either their effectiveness or safety. The four alternative systems discussed here reduce or eliminate these perverse incentives to varying degrees.

The Hollis system does the least to alter the basic incentive structure. Since firms will receive compensation based on their ability to lay claim to patents, they will have as much incentive as they do presently under the current system to withhold findings until they have claimed all potentially profitable patents. Similarly, since they will continue to reap rewards based on the sales of their drugs, they will have the same incentives to withhold evidence that questions the effectiveness or safety of their drugs after they have been placed on the market.

The Kremer auction system would leave in place the incentives for withholding information until all profitable patents have been claimed, but it would eliminate incentives to keep research secret concerning drugs that have already been placed on the

market. Since firms' profits do not depend on the sales of the drugs they developed after they have been placed on the market (assuming that they do not end up holding the patent), they have no incentive to conceal research findings that reflect negatively on the drug.

The exact incentive structure created by the Hubbard-Love system will depend on the details of how it is implemented. Since some intermediaries may choose to operate by offering prizes, there could still be incentive to withhold research findings prior to the development of drugs. Researchers who are competing for specific prizes will not want to share information and risk the possibility of aiding their competition.

Insofar as projects are directly funded, there would be minimal incentive to withhold research findings. Researchers reputations, and presumably their compensation, would increase by having their findings circulated as widely as possible -- thereby creating the opposite incentive. Similarly, researchers would have no stake in concealing any future findings that question the effectiveness or safety of specific drugs. Again, their reputations would be enhanced by having any such discoveries spread as widely as possible.

The Kucinich plan would produce a similar set of incentives, with the additional feature that a condition of being funded through one of the public research corporations is that all research findings must be made fully public in a timely manner. With openness as a standard operating procedure, not only would there be no obvious incentive for concealing research findings, as a practical matter, it might prove extremely difficult. It is much easier to conceal research findings in an institution were secrecy is the norm than in an institution where openness is the standard practice. It is likely that the Kucinch system would lead to a situation in which studies that raise questions about the effectiveness or safety of specific drugs are quickly brought to the attention of the medical profession and the public as a whole.

International Issues

All four of these systems are designed as mechanisms to support pharmaceutical research domestically, without explicitly providing for the sharing of research obligations across countries.[19] It is important to access how they could be integrated into an international system that ensures that the expense of pharmaceutical research is equitably shared among countries.

It is worth noting that the patent system does extremely poorly in this regard, as demonstrated by the controversy surrounding efforts to extend and enhance patent protections through trade agreements. These agreements invariably include complex

[19] The Hubbard-Love proposal is designed explicitly to be the domestic component of an international research treaty.

provisions, the meaning of which is hotly disputed even by experts in intellectual property law.

Of course, the underlying principles are not difficult – countries that hold large numbers of pharmaceutical patents, primarily the United States, want patent protection to extend as deeply as possibly internationally. However, since this implies the direct transfer of income from consumers in other countries in the form of higher drug prices (often much higher), efforts to extend patents will naturally be resisted. This is why the agreements often include ambiguous wording on issues like price controls or negotiated prices, compulsory licensing, and parallel imports. More precise wording could make it considerably more difficult politically to obtain parliamentary and popular approval of these trade agreements.

Even where approval of trade agreements can be obtained, there will always be ongoing problems of enforcement with the patent system. The same problems that exist domestically in maintaining a government granted monopoly exist in an international context, except that the immediate beneficiary of this monopoly will in many circumstances be a foreign corporation. It is not clear that governments will be able to maintain popular support for crackdowns against unauthorized production of patent protected drugs, especially when patent protection implies raising the price of life-saving drugs by several hundred percent above the competitive market price. Such enforcement actions will be very costly in any case, even if they do prove to be politically feasible. The pharmaceutical industry already frequently complains about the failure of developing countries to adequately enforce its patents. The problem can only get worse as patents come to apply to a broader category of drugs and the gap between the patent protected price and the competitive market price grows ever larger.

The four alternative systems would presumably involve a formal mechanism that would require research contributions from each country in some proportion to its income. While there would obviously be disputes over the exact formula that would be applied, the relative simplicity of the issues involved suggests that the solution is likely to be much simpler than trying to impose complex patent rules around the world.

Conclusion

Patent dependent financing for prescription drug research is leading to ever greater problems. The economic distortions associated with monopoly pricing are growing at a rapid rate, with the deadweight loss alone likely exceeding $100 billion annually within a decade. The waste associated with excessive marketing and sales efforts are growing at a corresponding rate. In addition, the corruption of the research process that is the predictable outcome of this form of government intervention in the market is becoming ever more pronounced. As a result, there is increasing interest in alternatives to the patent system for supporting prescription drug research.

This paper examines four of these alternatives. All four of them hold clear advantages over the patent system, most importantly all four systems would allow most drugs to be sold in a competitive market. Table 2 summarizes the assessments of the four systems by according to several important criteria.

Table 2

Rating Methods of Supporting Prescription Drug Research

	Patent System	Hubbard and Love	Hollis	Kremer	Kucinich
Marginal Cost Pricing	**1**	**5**	**5**	**4**	**5**
Excessive Marketing	**1**	**5**	**3**	**4**	**5**
Adequate Financing For Bio-Medical research	**4**	**4**	**5**	**3**	**4**
Incentives for Copycat Research	**1**	**5**	**4**	**4**	**5**
Political Interference in Research priorities	**4**	**3**	**3**	**5**	**3**
Secrecy of Research Findings	**1**	**4**	**2**	**2**	**5**
International Coordination	**2**	**4**	**4**	**4**	**4**

Ratings are on a scale of 1 to 5, with 5 being the best from a social standpoint. See text for the basis for the ratings.

While this assessment is obviously preliminary – and certainly does not consider all relevant factors, hopefully it will stimulate further discussion of the merits of these four proposals, as well as contribute to the development of other alternatives to the patent system.

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